



Prolapse: Room for Conservative Therapies

W28, 30 August 2011 09:00 - 12:00

| Start | End | Topic | Speakers |
|-------|-------|--|--|
| 09:00 | 09:05 | Introduction, Case study | <ul style="list-style-type: none"> • Helena Frawley |
| 09:05 | 09:20 | How do conservative therapies (pelvic floor muscle training, pessaries, lifestyle advice) work for prolapse? | <ul style="list-style-type: none"> • Ingeborg Braekken |
| 09:20 | 09:35 | Assessment: what does a physiotherapist do? | <ul style="list-style-type: none"> • Marijke Slieker-Ten Hove |
| 09:35 | 09:50 | Measuring success by outcomes | <ul style="list-style-type: none"> • Ingeborg Braekken |
| 09:50 | 10:10 | Treatment: what does a physiotherapist do? | <ul style="list-style-type: none"> • Ingeborg Braekken |
| 10:10 | 10:30 | A surgical perspective: integration of conservative therapies with surgery | <ul style="list-style-type: none"> • Jane Schulz |
| 10:30 | 11:00 | Break | None |
| 11:00 | 11:15 | Peri-operative physiotherapy as an adjunct to surgery | <ul style="list-style-type: none"> • Helena Frawley |
| 11:15 | 11:30 | Overview of the evidence for conservative management of prolapse | <ul style="list-style-type: none"> • Suzanne Hagen |
| 11:30 | 12:00 | Discussion | All |

Aims of course/workshop

The aims of this workshop are:

1. To present an overview of theory, rationale and the mechanism for conservative therapies (pelvic floor muscle training, lifestyle modification and pessaries) for pelvic organ prolapse (POP), and their role in the total management of this condition.
2. To present an overview of the physiotherapy clinical assessment of POP, and the value of various assessment tools.
3. To provide the gynaecologic perspective of what conservative therapies to recommend when, and when surgery is indicated.
4. To provide an overview of the role of conservative therapies as an adjunct to surgery for POP.
5. To present the evidence for conservative therapies in the prevention and treatment of pelvic organ prolapse (POP).

Educational Objectives

This workshop will address and present evidence for the role of all types of conservative therapies in the management of pelvic organ prolapse (POP) from conservative and surgical perspectives. Pelvic organ prolapse is a highly prevalent condition, and predicted to increase. To date, treatment options have been focused on surgery. This workshop will present the findings from recent research which confirms that conservative therapies have a valid and evidence-based role in the multi-disciplinary management of POP. An understanding of the theory and rationale for conservative therapies underpins the implementation of these therapies, and explains their place in the overall management of this condition. Topics will include pelvic floor muscle (PFM) assessment in women with POP and application of conservative therapies (PFM exercise, lifestyle advice and pessary management), utilising tools accessible to all clinicians. Knowledge of these assessment tools, strategies and intervention options will enable clinicians to implement these evidence-based options for treatment of POP in a timely and integrative manner.

Introduction to workshop

Case study

A case study will be used to illustrate the topic of this workshop.

Poppy, a 50 year old, para 2, presents with moderate bother of vaginal bulge. She has some co-existing mixed urinary incontinence, obstructed defaecation, and some lifestyle risk factors for prolapse. Poppy is keen to explore conservative therapies before considering surgery, and is not sure about a pessary. Poppy has received advice regarding pelvic floor muscle (PFM) exercise in the past but is not currently engaged in specific PFM training. In addition to home activities, Poppy undertakes some strenuous tasks at work and attends gym 1 x week. The rationale for PFM training for pelvic organ prolapse (POP), physiotherapy assessment and management of POP, use of a pessary, indications and guidelines for surgery, plus the evidence for conservative therapies for POP will be presented and discussed, highlighting the options applicable to this case study.

How does PFMT work for prolapse?

Ingeborg H Brækken, PhD, Physiotherapist

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Theory, rationale and mechanisms to explain how PFMT works in women with prolapse

2 main hypotheses: "The knack" or "bracing" prevents immediate descent whereas strength training builds up structural support over time (Bø & Frawley 2007¹).

What happens when Poppy contracts her muscles? (Ultrasound video)

Bracing "closes" the pelvic floor. Squeeze:

- From 20 to 15 cm²= 25% reduction in LH area (95% CI= 18-32) (Brækken et al 2008²)
- From 13 to 10 cm 21% reduction in muscle length (95% CI= 15-26) (Brækken et al 2008²)
- Mrs Poppy may reduce her hiatus somewhat less since POP women are more likely to have muscular impairments (DeLancey et al 2007³, Dietz & Simpson 2008⁴, DeLancey et al 2008⁵)

Bracing prevent organs to descent PFM contraction → Anterior- cranial lift:

- Bladder neck 0.5 – 1.2cm (Thompson et al 2005⁶, Reddy et al 2001⁷, Brækken et al 2009²)
- Cervix uteri 1.1 cm (Brækken et al 2009)
- Rectal ampulla 2.0 cm (Brækken et al 2009)
- Levator plate 2.0 cm (Brækken et al 2009)

More cranial than anterior movement

The displacement was 2x, or more, greater in the cranial versus anterior direction (Brækken et al 2009). Mrs Poppy may lift her organs less since POP women are more likely to have inability to elevate the levator plate (Thompson and Sullivan 2003⁸).

Hypothesis 1 – Bracing. No studies on the necessary strength or motor neuron control strategies to prevent cough induced descent. No evidence that the muscle strength will increase (Miller et al 2008⁹, Brækken et al 2010¹⁰) or result in any changes in morphology (Brækken et al 2010¹⁰). However Mrs Poppy is advised to do this when she coughs, sneezes and lifts to prevent immediate descent

Hypothesis 2 – PFMT. Can PFMT build up structural support of the pelvis?

Increased muscle strength is well demonstrated in women with SUI (Bø et al 1999¹⁴, Mørkved et al 2003¹⁵, Hay smith et al 2007¹⁶). Can Mrs Poppy build up her strength, when it is known that POP women have reduced muscle strength (Samuelsson et al 1999¹⁷, Nygård et al 2004¹⁸, DeLancey et al 2007¹⁹, Brækken et al 2009²⁰) and reduced muscle endurance (Brækken et al 2009)?

Yes: 0.5 increase in strength measured by mod. Oxford (Hagen et al 2009²¹), and 13.1 cmH₂O increase measured by vaginal pressure transducer (Brækken et al 2010²²).

Increased muscle thickness. 8% hypertrophy is shown for women with SUI (Balmforth et al 2006²³). But can it work for Mrs Poppy, when it is known that POP women have reduced muscle thickness (Hoyte et al 2004²⁴, Chen et al 2006²⁵)?

Yes: 17% increase in muscle thickness (Brækken et al 2010)

Narrowing the levator hiatus

Never previously been shown. Can it work for Mrs Poppy, when it is known that POP women have: reduced vaginal resting pressure (DeLancey et al 2007¹⁹, Brækken et al 2009²⁰) and enlarged hiatal area (Berglas & Rubin 1953²⁶, DeLancey & Hurd 1998²⁷. Ghetti et al 2005¹³, Hoyte et al 2001²⁸, Singh et al 2003²⁹).

Yes: PFMT may lead to reduction in hiatal area. Brækken et al found 7 %reduced hiatal area, with a differences of 1.8 cm².

Measuring success by outcomes:

Dr Ingeborg H Brækken

Outline

- Subjective outcomes
 - Prolapse, bladder, bowel symptoms
 - incl quality of life measures
- Objective
 - PFM Function
 - Position of the organs
 - POP-Q
 - Ultrasound
- Morphological changes of the PFM muscles
 - Muscle thickness
 - Size of hiatus
 - Muscle length
 - Functional changes of the PFM muscles
 - Muscle length and size of hiatus at maximum Valsalva

Standardized questionnaires

- Australian PF Questionnaire (Baessler et al 2010³⁰)
 - POP-SS (Hagen et al 2009³¹)
 - ICIQ-VS (Price et al 2006³²)
 - Prolapse Quality of Life (P-QoL) (Digesu et al 2005³³)
 - Pelvic Floor Distress Inventory (PFDI) (Barber et al 2001³⁴)
 - Pelvic Floor Impact Questionnaire (PFIQ) (Barber et al 2007³⁵)
 - Symptoms and bother in POP (Mouritsen & Larsen 2003³⁶)
 - Urogenital Distress Inventory (Shumaker et al 1994)
 - A short-form questionnaire identified genital organ prolapse (Tegerstedt et al 2005³⁷)
- Important to cover frequencies and QoL measures. Tested for validity in the actual population.

POP may persist with a combination of symptoms

Measuring success

- Can success be expected if strength training does not improve strength?
 - Can improved strength be expected if participants do not adhere to the training?
- Adherence/ dropout:
- Hagen et al 2009: 61% of the participants adhered at moderate and good levels. Drop out: 13 and 15% questionnaire, 11% gynaecology appointment
 - Braekken et al 2010: Home exercise=89%, PT visits = 83%. Two (1,8%) dropped out
 - Not described/ assessed: Piya-Anant et al 2003; Ghroubi et al 2008?

PFM Function: strength

Hagen et al 2009:

- Improvement 0.5 +/- 0.6 Oxford scale p=0.008 (Controls not tested)

Braekken et al 2010:

- Improvement: 13.1 (10.6 – 15.5) vs 1.1 (0.4-2.7) cmH₂O p<0.001 Effect size: 1.21
- Not described/ assessed: Piya-Anant et al 2003; Ghroubi et al 2008?

PFM Function: endurance

Braekken et al 2010: Improvement: 107 (77-136) vs 8 (-7 – 24) cmH₂Osec. The effect size: 0.96.

PFM Function: resting pressure

Braekken et al 2010:

- No significant difference in improvement between groups for vaginal resting pressure.

Prolapse symptoms

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008:

- Pelvic heaviness persisted in 19% (PFMT) vs 70% (control) p<0.001

Hagen et al 2009:

- 3.5 vs 0.1 decrease in POP-SS score p=0.021
- No sign changes in vaginal symptoms

Braekken et al 2010:

- 74% vs 31% reduced episodes of vaginal bulging/ pelvic heaviness episodes p<0.001

Bladder symptoms

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008:

- Significant reduction in “measurement of urinary handicap”, maximum urethral closure pressure $p < 0.001$

Hagen et al 2009:

- No significant changes in ICIQ-UI-SF

Braekken et al 2010:

- 74% vs 30% reduced numbers of SUI episodes $p < 0.001$
- 55% vs 33% reduced numbers of UUI episodes $p = 0.042$
- ICIQ-UI-SF improvement: 2.6 (95%CI: 1.0-4.3), $p < 0.001$, Effect size: 0.62

Bowel symptoms

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008: not described/ assessed

Hagen et al 2009:

- No significant changes

Braekken et al 2010:

- 53% vs 22% reduced numbers of flatus episodes $p = 0.002$
- No significant improvement in emptying of bowel or fecal incontinence

Sexual symptoms

- ?

Stage of POP

Piya-Anant et al 2003 (visualized)

- Mild degree of POP: no changes
- Severe degree of POP: 28% vs 72% worsening of POP ($p = 0.005$)

Hagen et al 2009

- POP-Q: 5/11 (45%) vs 0/9 ($p = 0.038$)

Braekken et al 2010

- POP-Q: 11/58 (11%) vs 4/50 (8%) ($p = 0.04$)

Improvement POP-Q:

Trend: Increasing improvement rate with increasing stage of POP ($p = 0.06$) (Braekken et al 2010)

Corresponds with Piya-Anant et al 2003

POP-Q:

Valsalva → PFM are stretched and pushed in a caudal direction

Opposite to the PFM function!

Hence, an improvement in POP-Q may not be expected

3D/ 4D Ultrasound Used by Braekken et al 2010

Elevated organs

Bladder: 4.3 mm (95%CI 2.1 – 6.5), $p < 0.001$, Effect size: 0.75

Bowel: 6.7 mm (95%CI 2.2 – 11.8), $p = 0.007$, Effect size: 0.65

Correlation with increase in PFM strength

- Bladder elevation ($r = 0.23$, $n = 94$, $p = 0.024$)
- Bowel elevation ($r = 0.27$, $n = 74$, $p = 0.019$)

Functional changes

- Reduced hiatal area at Valsalva

Differences 2.3 cm^2 (95%CI -0.1 – 4.8, $p = .02$), Effect size: 0.43

- Reduced muscle length at Valsalva

Differences 11.0 mm (95%CI 3.4 – 18.5, $p = .001$), Effect size: 0.65

Morphological changes: Muscle thickness

Differences **1.9 mm** (95%CI 1.1 – 2.7, $p < .001$, Effect size: 0.85)

Morphological changes: Reduced hiatal area

- 7 % reduced hiatal area
- Differences 1.8 cm² (95%CI 0.4 – 3.1), Effect size: 0.51

Morphological changes: Shortened muscle length

- 5 % shortened muscle length
- Differences 6.1mm (95%CI 1.5 – 10.7, $p = .007$), Effect size: 0.52

Functional changes

Reduced muscle length and hiatus size at maximum Valsalva

Indicates increased “stiffness” in the musculo-connective tissue complex

Possible explanations:

- amount of collagen and muscle tissue
- changes in muscle architecture
- altered structure of connective tissue Folland et al 2007

Morphological changes: No difference occurred within the control group ($p > 0.11$)

PFMT has the possibility to “tighten up” the pelvic floor

Conclusion: PFMT can:

- reverse POP (POP-Q) in some women
 - Elevate the bladder and bowel
 - Reduce mechanical, bladder and bowel symptoms
 - Increase muscle volume
 - Reduce the levator hiatus
 - Shorten PFM length
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Assessment: what does a physiotherapist do?

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Pelvic Floor Dysfunction (PFD) is an umbrella term for many signs and symptoms and is often more confusing than clarifying. For example, it is too general, as it does not indicate the exact location of a particular dysfunction. This is understandable, because the pelvic floor consists of connective tissue, ligaments, fascia and muscle fibres that all have different functions, while within health care, many different specialists are involved, who have their own field of expertise, but nevertheless try to integrate their efforts. It is therefore important to focus on the different aspects of the pelvic floor and the pelvic organs, before combining these elements into a functional diagnosis. For a physiotherapist, the greatest interest is in the role of the pelvic floor muscles (PFM) in the total function of the pelvic floor and their relation to PFD. In patients with PFD, the most important application for a physiotherapist is to provide conservative treatment by working on the PFM.

The tonic (constant) contraction of the puborectalis muscle, part of the levator-ani-complex, closes the urogenital hiatus and contributes to the horizontal axis of the proximal vagina and levator plate (Strohbehn, 1998). In a woman without prolapse, in the upright position, the proximal vaginal axis is nearly horizontal, lying on the parallel levator plate. Studies have shown that as intra-abdominal pressure increases, the pelvic diaphragm contracts and maintains the position of the levator plate and horizontal vaginal axis (Nichols et al. 1970, Harris and Bent 1990, Nicols 1992). As a consequence, the uterus, vagina and rectum are pushed against the levator plate, but not through the genital hiatus. Connective tissue and striated muscles maintain the support of the posterior wall (DeLancey, 1999). Contraction of the levator ani muscles closes the vagina and relieves the connective tissue of constant load and with normally functioning levator ani muscles, no stress will occur on the mid-vagina support (DeLancey1992a). Therefore the diagnostic process will be intensively focussed on the PFM function.

Assessments

Pelvic physiotherapists take a history covering all details of the pelvic floor like bladder, bowel, uterus and sexual function questionnaires for quality of life, e.g. the Euroqol, VAS and IIQ. In addition the pelvic organ prolapse symptom score (POP-SS) (Hagen et al., 2009) can be used to score changes in pelvic organ prolapse symptoms. The pelvic floor musculature is part of the musculoskeletal system and therefore has an integrated function with abdominal and back musculature. That is why assessment of posture, pelvis and lumbar spine will be part of this assessment. For the assessment of PFM physiotherapists use a standardized assessment scale to test the pelvic floor musculature digitally, for both voluntary and involuntary contractions. In addition to this assessment, different techniques can be used: electromyography(EMG), manometry, ultra sound and in hospital settings MRI. All methods of assessment have their strengths and weaknesses, which will be briefly presented.

For physical examination of POP, the POP-Q has been developed, as a validated and internationally accepted method. This validation was based on assessment by a gynaecologist. However, recently the feasibility, inter- and intra-rater reliability of the POP-Q by physiotherapists has been demonstrated, although the physiotherapy examination time was shown to be significantly longer. Aside from the POP-Q, the question remains how to test PFM function (Stark et al., 2010). In addition to the function of the PFM, intra abdominal pressure seems to play an important role in developing and/or worsening POP or incontinence (Slieker et al., 2009). When connective tissue and reflex contraction of the PFM are not able to control the location of the pelvic organs there must be a possibility for the

(conscious contracting) striated musculature to create some effect. Striated muscles can be contracted consciously and therefore can be trained with different goals. Although observed in a small group, PFM also seem to contract in voluntary or reflex co-activation with abdominal muscles (Sapsford et al., 2001, Devreese et al., 2004). Some patients present a dysfunctional co-contraction between PFM and abdominal muscles. When the patient squeezes or coughs, a caudal displacement of the pelvic floor can occur (Slieker et al., 2009). This displacement is well known but is this due to weakness or to poor coordination? Before commencing any treatment this needs to be assessed via the diagnostic process of the physiotherapist.

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Treatment for 'Poppy'

- Descended organs → PFMT
- Prolapse & urinary symptoms
→ PFMT + bracing
- Information: Reduce modifiable risk factors
- Weak PFM → strength training (PFMT)
- High BMI → nutrition, physical activity
- High IAP (lifting, gym) → minimize numbers of heavy lifting + bracing
- Obstructed defecation → nutrition, fluid, toilet habits???
- If she can't contract → Adjunctive therapies
- If it doesn't work → easily removable pessary
- If this doesn't work → surgery if motivated

Treatment (Hagen et al 2006⁴⁰, Maher et al 2007⁴¹)

460-370 B.C. "Hippocratic succession" Apollonius von Kittum 1896⁴²

- Surgery
- Conservative
- Pessaries (mechanical)
- Information/ Lifestyle advice

Surgery

- About 11% of all women will undergo surgery for POP or incontinence (Olsen et al 1997⁴³)
- 41- 58% occurrence of recurrent POP (Miedel et al 2008⁴⁴, Whiteside et al 2004⁴⁵)
- 10 - 29% re-operations (Miedel et al 2008⁴⁴, Olsen et al 1997⁴³)

Pessaries

- Sexual active
→ removable ring
- POP+SUI
→ Ring with support
- Cystocele
→ Ring with support
- Third degree POP
→ Donut, Gellhorn

Information – lifestyle advice

Lifestyle advice modification

- Avoid straining (Lubowski et al 1988)
- Especially during defecation
- hiatal ballooning (Dietz et al 2008⁴⁶)
- Ultrasound video of a Valsalva Maneuver

Information – Reduce modifiable risk factors

- High BMI (Progetto Menopausa Italia Study Group 2000⁴⁷, Moalli et al 2003⁴⁸)
- Increases in IAP (coughing, lifting, etc) (Rinne & Kirkinen 1999⁴⁹)
- Poor PFM function (DeLancey et al 2007¹⁹, Brækken et al 2009²⁰)
- Constipation (Arya et al 2005⁵⁰, Hendrix et al 2002⁵¹)
- Avoid delay to defecate
- Fluid, nutrition
- Vigorous physical activity? (Delancey et al 2008⁵ vs Brækken et al 2009²⁰)
- Smoking?

Information – Bracing/ “The Knack”

Bracing for rises in intra-abdominal pressure. The Knack” when coughing or sneezing (Miller et al 2001⁵²)

Finding the muscles/ Correct technique

>30% incorrect contraction (Benvenuti et al 1987⁵³, Bump et al 1991⁵⁴, Bø et al 1988⁵⁵, Kegel 1948⁵⁶). Lift and squeeze should be present (video-clip)

Facilitation techniques

If not able to identify the muscles:

- Facilitation technique
- Tapping
- Stretching
- Information – practice for 1 week
- Adjunctive therapies

Adjunctive therapies

To visualize the contraction pressure manometry, real-time ultrasound and surface EMG can be used. To enhance the contraction electrical stimulation can be used.

PFMT Aim to strengthen the PFM. Different approaches: PFMT, Vaginal cones (VC), EI. Stimulation (ES). This has not been evaluated in women with POP, but SUI:

- ICI Grade B recommendations: Intensive PFMT is better than VC alone and ES alone (Hay Smith et al 2009⁵⁷)

Protocol Piya-Anant et al 2003³⁸: 30 contractions per day (after a meal), Duration: 2 years, Follow-up visits every 6th months, Advised to eat more vegetables and to drink >2 liters of water per day

Protocol Hagen et al 2009²¹ 6 sets of 20 contractions (10 slow and 10 fast) per day for 4 months, Exercise diary, 5 PT visits , ”The knack”. Both control and PFMT group received lifestyle advices (change from high to low impact exercise, kneel instead of squat when gardening)

Protocol Brækken et al 2010²² (POP study) used strength training principles from sports science (Repetitions, Duration, Frequency, Positions) 3 sets of 8-12 contractions per day. 6 months to enhance hypertrophy, 18 PT visits, Exercise diary, Both control and PFMT group received lifestyle advices

Adherence = $\alpha\Omega$. Women who do not adhere do not get stronger

- > 80%, Can’t expect training to work if not training!

Which protocol is best? ICI, Level A: Best results of PFMT (SUI) when:

- Supervised training, > 3months, Intensive training: ICI, Hay Smith et al 2009⁵⁷; Bø et al 2007⁵⁸

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A surgical perspective: integration of conservative therapies with surgery

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Pelvic organ prolapse is seen in up to 50% of parous women (Swift 2000). Although often asymptomatic, it may present with symptoms of bulging, pelvic pressure and occasionally backache. It is often associated with bladder, bowel and sexual dysfunction. Treatment options include: surgical correction, use of mechanical vaginal devices (pessaries) and/or conservative approaches such as pelvic floor muscle therapy.

There is increasing evidence that a multidisciplinary team approach to managing patients with pelvic floor dysfunction is preferable (Chan et al.2010). Although the composition of these teams is variable, they often include nurse continence advisors, physiotherapists, urogynecologists, urologists, and colorectal surgeons. Nurse-run clinics are a viable option for providing pessary care (Hanson et al. 2006).

A pessary is a device placed into the vagina to either support the prolapsing vaginal walls or provide urinary continence. Pessaries have the distinct advantage of being minimally invasive and provide immediate relief of symptoms. Although in the past, pessaries had been reserved for the frail and elderly, they are also an excellent alternative for symptomatic women who have not finished childbearing or choose a nonsurgical intervention. Pessaries are experiencing resurgence in popularity and remain a viable option for prolapse and incontinence for women in any age group (Hanson et al. 2006).

Pessaries are primarily made of medical grade silicone with only the largest sizes having covered surgical steel. This has the advantage of making them inert and less likely to have an odour and cause an allergic reaction (Baessler et al. 2009). Pessaries used for the treatment of prolapse can generally be classified into support pessaries or space occupying pessaries (Towbridge et al. 2007). The support pessaries sit in the posterior fornix and generally rest above the pubic bone and/or pelvic floor. The commonly used ones include the ring pessaries (with or without diaphragms) and the Shatz pessaries. The space occupying pessaries include the cube, inflatable and donut pessaries: the cube works by bringing the vaginal walls towards the midline and the others occupy a larger space than the introitus. They are most often used for more severe prolapse. The commonly used Gellhorn works as a combination of these two methods (Towbridge et al.2007). There are many other styles to address specific defects but their use is not often reported in the literature.

If successful in the first 4 weeks of fitting, pessaries have good long-term success for management of pelvic organ prolapse without a concomitant increase in complications (Lone et al. 2011).

Many women want a quick fix for their prolapse. However, durability of surgical cure varies widely, as do functional outcomes. Pelvic floor muscle therapy as a pre- and post-operative adjuvant to any management of prolapse, is logical and may provide assistance with managing functional complaints (Jarvis et al. 2005), in addition to educating women regarding restrictions and exercises that may help improve the durability of their repair. Defining success after prolapse surgery is difficult. The absence of vaginal bulge symptoms postoperatively has a significant relationship with a patient's assessment of overall improvement, while anatomic success alone does not (Barber et al. 2009). However, it is very important that the surgeon is mindful of the following goals when contemplating pelvic floor reconstruction (Drutz et al 1998):

- restore and/or maintain urinary and fecal continence
- reposition pelvic structures to normal anatomic relationships
- maintain sexual function

- correct coexisting pelvic pathology
- alleviate abnormal symptoms
- obtain a durable result

There exist multiple guidelines internationally for the management of urinary incontinence. However, practice guidelines and management algorithms are far less common for pelvic organ prolapse (4th ICI 2010). Evidence is still lacking for managing pelvic organ prolapse in a multidisciplinary manner.

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Conservative therapies as an adjunct to surgery.

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Historical perspective:

- Kegel (1956) PFEx advocated for treatment of UI & genital prolapse:
 - “or as an adjunct to surgical repair”.

Does quality of muscle play a role?

Does peri-operative physiotherapy enhance long-term functional outcomes?

Why bother adding to surgery?

- Surgery is common: lifetime risk for POP/UI surgery: → 11 – 11.8% (Olsen et al 1997, Fialkow et al 2008)
- Surgery has a failure rate: up to 66% at 3 mths (Iglesia et al 2010)
- Re-operation affects ½ - 1/3 (Olsen et al 1997, Whiteside et al 2004)
- Urgent need for strategies to prevent re-operation: → 25% improvement in surgical success ↓ 2nd operation for 30,000 women (DeLancey 2005)
- Previous gynaecological surgery: a ‘risk’ event (Clark et al 2003, Moallie et al 2003, Tegerstedt et al 2004) → target these high risk patients

What does surgery change?

- structural defects: ✓
- co-existing bladder / bowel / sexual symptoms: ?
- inherent risk factors: ✗
- potentially modifiable risk factors (incl pelvic floor muscle strength and function): ✗

Do we have guidelines?

- Clinical practice:
 - Surveys of gynaecologists (Fitzgerald et al 2001, Ottesen et al 2001)
 - Survey of Australian physiotherapists (Frawley et al 2005)
 - ⇒ Inconsistency, enormous variation exists
 - ⇒ No evidence-based established guidelines
 - ⇒ Clinical recommendations in teaching texts
- Intervention studies (RCTs):
 - ✓ *Jarvis et al 2005*
 - ✗ *Frawley et al 2010*
 - ⇒ Equivocal results to date (Frawley 2010)

General rationale

- Soft tissue trauma:
 - Tissue trauma and healing principles
 - Muscle atrophy / inhibition
- Rehabilitation
 - Parallels with general surgical rehabilitation and early post vaginal childbirth protocols
 - Pre- / peri- / post-op muscle strengthening?
 - Post-op restrictions: lift / strain / cough
 - Resumption of ADL and general exercise levels
- Address residual / *de novo* related symptoms

Early post-op: Breathe, cough, wriggle the toes?

- Pelvic surgery: low risk event for pulmonary complications
 - No evidence that routine respiratory and circulatory physiotherapy is required

(Pappachan et al 2006, Smetana et al 2006, Scholes et al 2009)

What can be done to help Poppy's surgical outcomes?

- Quality and function of PFM tissues
- Lifestyle factors
- +/- other symptoms
 - Residual or *de novo* UI, FI, obstructed defecation

Early post-op: relative rest

- Rest for healing vs normal physiologic functions → impossible to rest or immobilise PF
- Study of vaginal pressures in women: not POP, not surgical cohort: several exercises produce less vaginal pressure rises than bearing down and coughing (O'Dell et al 2007)
- 317 subjects assessed pre-op POP surgery. Strongest PFM: less advanced POP, smaller genital hiatus measures, less urinary symptom burden (Borello-France et al 2007)

Effect of vaginal POP surgery on PFM strength

- Comparison of pre-operatively to 3 months post-operatively:
 - reduction in PFM strength in the CG (-1.8 cmH₂O [Jarvis et al 2005], - 2.9 cmH₂O [Frawley et al 2010])
 - improvement in PFM strength in the TG (2.7 cmH₂O [Jarvis], 4.1 cmH₂O [Frawley])
- 358 women undergoing POP surgery: stronger pre-op PFM strength → ↓post-op POP and ↓repeat surgery (Vakili et al 2005)

What can be done to help Poppy's surgical outcomes?

- Quality and function of PFM tissues
- Lifestyle factors
 - Generation of intra-abdominal pressure
 - BMI / central adiposity
 - +/- other symptoms
 - Residual or *de novo* UI, FI, obstructed defecation

Vaginal pressure during daily activities before & after vaginal repair

- Based on measurements of vaginal pressure rises during routine activities, compared with pressure rises due to a PFM contraction, Mouritsen et al., (2007) considered PFM exercises "safe" to do immediately following vaginal prolapse repair
- intra-vaginal pressure generation (=strength) from a PFM contraction at day 1 – 3 post-operatively was less than pre-operatively, and remained so at 4 – 6 weeks post-operatively → suggests that PFM strength may be reduced following vaginal prolapse surgery.
- Mean VP was four to five times higher during coughing and Valsalva compared to PFC and lifting 2 and 5 kg, therefore post-operative counseling should concentrate more on treating chronic cough and constipation than restrictions of moderate physical activities.

IAP pressure generation: not just how much, but how it's done

- Squatting vs assisted squatting vs lifting from a counter vs receiving the weight: significant differences in pressure generation (Gerten et al 2008)

Evidence from RCTs

1. Jarvis et al 2005:

- investigated the effect of pre- & post-op physiotherapy on 60 women undergoing POP/UI surgery
- Treatment Group received 3 x physiotherapy-supervised PFMT sessions, bladder training, and bowel training.
- Outcomes measured changes in continence, quality of life, and general health symptoms 6 months postoperatively.
- Results indicated a significant improvement in quality of life and urinary symptoms for the TG
- Results were presented for the combined surgical cohort.

2. Frawley et al 2010

- Primary outcomes:
 - Control group & Treatment Group: improvements in bladder, POP and bowel symptom scores following surgery
 - differences between groups: not significant after adjusting for baseline differences (trend towards more improvement for TG)
- Secondary outcomes:
 - Between-group differences were significant in favour of TG for:
 - Pelvic floor muscle strength (digital testing)
 - Assessment of Quality of life
 - General exercise participation: frequency of exercise / week

Future research

- Operations and pelvic muscle training in the management of apical support loss (OPTIMAL) trial: (Barber et al 2009)
<http://clinicaltrials.gov/ct2/show/NCT00597935?term=OPTIMAL+trial&rank=1>
 - 1) to compare surgical outcomes following sacrospinous ligament fixation to uterosacral vaginal vault suspension in women undergoing vaginal surgery for apical or uterine POP & SUI
 - 2) to examine the effects of a structured perioperative program consisting of behavioral techniques and PFMT vs usual care.
 - N=440; Study completion expected March 2013
- SURgery and Physiotherapy for prolapsE Recurrence (SUPER): a feasibility study: aim is to evaluate the effect of peri-operative physiotherapy in women undergoing POP / UI surgery (McClurg D, Hagen S, Hilton P, Dolan L, Monga A, Frawley H)
 - Recruitment commenced

What to advise Poppy?

- Adequate (excellent) course of pre-operative PFMT and lifestyle modification
- Post-operative in-patient physiotherapy to ensure PFM contraction and re-inforce advice
- Post-operative PFMT, lifestyle advice, graduated return to 'full' activity: ADL and general exercise

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Overview of the evidence for conservative management of prolapse

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- **ICI Committees Paris, France - July 5-8, 2008**
- Evidence available
- Levels of evidence
- **Level 1 evidence (incorporates Oxford 1a, 1b)** usually involves meta-analysis of trials (RCTs) or a good quality RCT
- **Level 2 evidence (incorporates Oxford 2a, 2b and 2c)** includes “low” quality RCT or meta-analysis (with homogeneity) of good quality prospective ‘cohort studies’
- **Level 3 evidence (incorporates Oxford 3a, 3b and 4)** includes: good quality retrospective ‘case-control studies’ with appropriate matching (e.g. for age, sex etc). good quality ‘case series’ where a complete group of patients all, with the same condition/disease/therapeutic intervention, are described
- **Level 4 evidence (incorporates Oxford 4)** includes expert opinion where the opinion is based not on evidence but on ‘first principles’ (e.g. physiological or anatomical) or bench research

Cochrane reviews on prolapse treatment

- Surgery *Maier, Feiner, Baessler, Glazener. 2010*
 - 40 trials, 3773 women
 - Some evidence re vault, anterior, posterior repair
 - Not enough evidence on most types of common prolapse surgery nor about the use of mesh or grafts
- Mechanical devices *Adams, Thomson, Maier, Hagen 2004*
 - No published trials
 - Not enough evidence about the effects of mechanical devices (pessaries) on managing prolapse
- Conservative management *Hagen, Stark, Maier, Adams 2006*
 - 3 trials (1 sizeable)
 - Insufficient evidence to guide practice
- Oestrogen
 - Ismail SI, Bain C, Hagen S. Oestrogens for treatment or prevention of pelvic organ prolapse in postmenopausal women. *Cochrane Database of Systematic Reviews* 2010, Issue 9. Art. No.: CD007063. DOI: 10.1002/14651858.CD007063.pub2.
- Lifestyle: risk factors for prolapse
 - Familial transmission *Tegerstedt O&G 2009*
 - Ethnicity *Whitcomb AJOG 2009*
 - Socioeconomic factors
 - Occupation/heavy lifting *Tegerstedt O&G 2009*
 - Obesity *Whitcomb IJU PFD 2009* (contradicted by *Washington 2010*)
 - Vitamin D *Badalian O&G 2010*
 - Obstructed defaecation *Tegerstedt O&G 2009, Saks 2010*
 - Hysterectomy
 - Childbirth/CS/obstetric factors *Larsson 2009*

Lifestyle interventions: prevention

- No prospective studies
- Evidence of association between prolapse and

- Heavy lifting/strenuous physical activity (LE 3)
- Being overweight (LE 3)
- Constipation (conflicting findings, poor quality)
- Anaemia (one study)
- Irritable bowel syndrome (one study – *Wang 2010*)
- Potential for prevention trials? Unlikely.
- Long-term follow-up required

Lifestyle interventions: treatment

- No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the treatment of women with prolapse

PFMT: prevention

- Relationship between pelvic floor function and prolapse (LE 2):
 - Borello-France 2007
 - Braekken 2009
 - Slieker Ten-Hove 2009
 - Moen 2009
- Secondary analysis:
 - Glazener ICS 2010 – ProLong Study, prolapse 12 years after childbirth; subgroup of women were in trial of PFMT

PFMT: treatment

- Overview
 - Piya-anant
 - Ghroubi
 - Hagen (feasibility trial)
 - Braekken (LE 1)
 - Hagen (trial) (LE 1)
- Updated Cochrane review due 2011
 - Conservative management *Hagen, Stark, Maher, Adams 2006*
 - 3 trials (1 sizeable)
 - Insufficient evidence to guide practice

Piya-anant et al 2003

- Elderly (60yrs+) community sample, Thailand
- Anterior prolapse
- Symptomatic?
- 330 intervention/324 control
 - unspecified PFExs training
 - dietary advice
- 6 and 24 month follow-up
- No objective prolapse measurement
- PFExs effective in women with severe prolapse
 - @ 24mths 72.2% worse in control vs 27.3% in intervention

Ghroubi et al 2008

- 47 women with stage I or II cystocele, randomised to PFM exercises + healthy living advice or control group
- Outcomes: clinical examination, the “Measurement of Urinary Handicap” (MUH) scale, urodynamic tests, the Ditrovie quality of life scale, patient satisfaction
- immediately post-treatment, pelvic heaviness persisted in 5 (19%) in treatment group vs 14 (70%) in the control group ($p < 0.001$)
- significant differences in quality of life and urodynamic measures in favour of treatment group

- 20 women from the treatment group retained benefits two years after the treatment had ceased
- Hagen et al 2009 - methods
- feasibility trial, 47 women randomised to PFMT (n=23) or control n=24) group
- stage I or II symptomatic prolapse of any type, 2 UK centres.
- Intervention: 5 physiotherapy appointments over 16 weeks, with an individually-prescribed daily PFM exercise programme. Control women received a prolapse lifestyle advice leaflet by post only.
- Outcomes: blinded POP-Q; prolapse-related symptom severity and quality of life; PFM strength (modified Oxford scale) intervention group only.
- Follow-up at 6 months

Hagen et al 2009 - results

- PFMT group more likely than controls to have an improvement in prolapse stage (45% vs 0% improved, Fisher's exact test $p=0.038$).
- Intervention group had significantly greater improvement by 6 months than controls in their prolapse symptom score (mean score decrease 3.5 versus 0.1, $p=0.021$).
- PFMT group more likely to report their prolapse was better now than at the start of the study (63% vs 24% at 6 months, $p=0.012$)
- A significant improvement in PFM strength was detected in the intervention group; mean muscle strength increased by 0.5 on the modified Oxford scale (95% CI 0.2 to 0.8, $p = 0.008$)

Braekken et al 2009, 2010 - methods

- RCT of 108 women, stage I, II or III
- Intervention: n=59, instructed in PFMT for 6 months with home exercise
- Control: n=50
- Both groups: lifestyle advice, "the Knack"
- Outcomes: POP-Q, symptoms, ultrasound
- Follow-up at 6 months

Braekken et al 2009, 2010 - results

- Improved POP-Q by 1 stage: 19% PFMT vs 8% control
- Position of bladder and rectum significantly higher in PFMT group
- PFMT group had:
 - Increased pubovisceral muscle thickness
 - Decreased hiatal area at rest/valsalva
 - Shortened muscle length at rest/valsalva
 - Increased muscle stiffness
- Relevant ongoing research - PFMT

Treatment: POPPY Trial (Hagen)

- PFMT or prolapse (n=448)
- 16 week/5 appointment intervention
- 1 year follow-up symptoms and severity
- Trial to report ICS 2011 (Thursday 1st)

Prevention: PREVPROL (Hagen)

- Prevention of symptoms in non-symptomatic women with some vaginal laxity
- Recruited from longitudinal cohort
- Over 300 women randomised

Picture of pessaries (support and space –occupying)

- Pessaries: treatment
- Cundiff: RCT of Gelhorn vs ring (LE 2)

- Lukban: uncontrolled study of colpexin sphere
- Harnsomboon (2011): RCT of colpexin sphere in women with prolapse
- Kapoor: uncontrolled study of pessary vs surgery
- Abdool (2011): non-randomised study of pessary vs surgery
- ATLAS Trial: PFMT +/- pessary for UI (March 2010) – prolapse women included?

Cochrane review – to be updated 2011 (Reid et al)

- Mechanical devices *Adams, Thomson, Maher, Hagen 2004*
 - No published trials
 - Not enough evidence about the effects of mechanical devices (pessaries) on managing prolapse

Cundiff et al 2007 - methods

- multi-centre crossover RCT, ring with support vs Gellhorn pessary.
- 134 women randomised; 71 to ring pessary with support and 63 to Gellhorn, followed by crossover to the second type of pessary, ring with support (n=54) or Gellhorn (n=54).
- stage II or greater symptomatic prolapse, no prior pessary experience.
- 48% had stage II, 42% stage III and 10% stage IV prolapse.
- 51% had anterior prolapse.
- Mean age 61 years, most women parous and post-menopausal.
- no significant differences between groups at baseline.
- fitted with 1st pessary for 3 months, then 2nd pessary for 3 months.
- Follow-up: during each 3-month period data collected at 1, 6 and 12 weeks from women with successful fit.
- 1 year appointment to discuss pessary continuation/other treatment.
- Outcomes measured at enrolment and 3-months: POP-Q, PFDI, PFIQ, sexual function questionnaire.

Cundiff et al 2007 - results

- Combining the two trial periods there were complete data on the ring pessary from 94 women, on the Gellhorn from 99, and on both pessaries from 85.
- statistically significant improvements in the majority of PFDI and PFIQ scale scores for both pessaries, including the prolapse specific sub-scores (POPDI for symptoms and POPIQ for impact).
- no differences between pessaries in improvement in these two sub-scores (POPDI, p=0.99; POPIQ, p=0.29).
- all POPDI sub-scores showed clinically significant improvements for both pessaries. Only for the Gellhorn were there clinically significant improvements in impact of prolapse symptoms (POPIQ), and only then for the physical sub-score and the total POPIQ score.
- Women who were highly satisfied with the Gellhorn also had improvement in a range of symptoms including the POPDI score; no similar significant association was found for the ring pessary with support.
- Relevant ongoing research - pessaries

OPTIMAL Trial (Barber)

- Vault surgery +/- PFMT
- Trial to report 2012

PEPPY Study (Hagen, poster ICS 2011)

- Feasibility study
- PFMT +/- pessary for prolapse

Case study – Poppy

Would lifestyle modification help Poppy?

- We can't make E-B recommendations but epidemiological studies suggest obesity, heavy lifting and possibly constipation may play a role, and Poppy could be advised on these as appropriate

Would PFMT help Poppy?

- Most rigorous evidence to date suggests that PFMT would help reduce the anatomical prolapse and the associated symptoms up to 12 months

Would pessary help Poppy?

- Preference is a factor, as is the skill/patience of the clinician. If she were to opt for a pessary no difference between ring with support and Gellhorn

If Poppy was to opt for surgery, would PFMT as an adjunct help?

- We can't make evidence based recommendations. Small controlled trials to date haven't shown an effect. Larger trial of surgery +/- PFMT in vault prolapse is underway.

Conclusions re. Conservative options

- What do we have strong evidence for?
 - Association between pelvic floor muscle function and prolapse
 - PFMT, supervised 6 month programme, and 16 weeks programme
 - Ring with support and Gellhorn
- What do we have little/no evidence for?
 - Lifestyle modifications eg. weight loss
- What should evidence-based advice be for our patients?

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